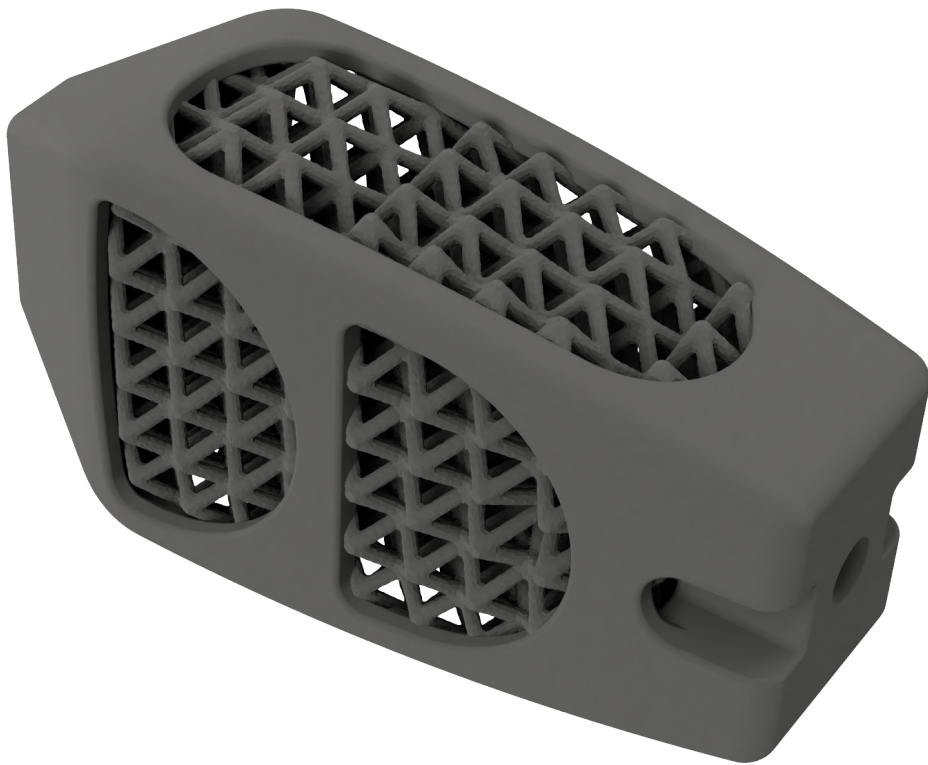


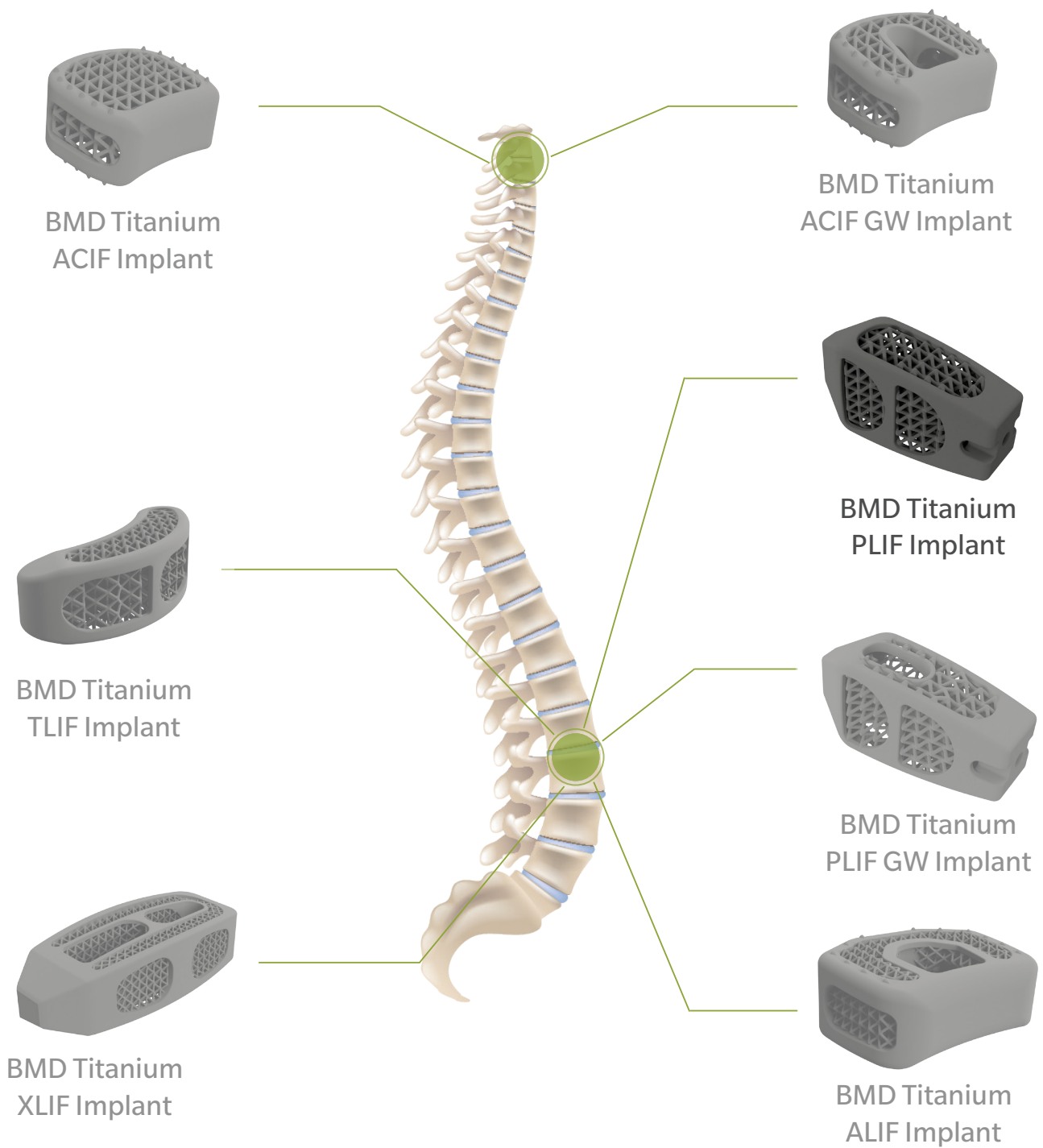


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The Lumbar BMD
Titanium PLIF Implant[®]

Surgical Technique Guide



3D-printed spinal fusion Global BMD Titanium Implants®

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The following general Surgical Technique Guide is for illustrative purposes only. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as to the best treatment for each patient. Only those individuals with specialized training and experience in spinal surgery should attempt to use the BMD Titanium PLIF Implant[®]. Detailed preoperative clinical and diagnostic evaluation followed by carefully executed surgical technique is essential. Refer to the Instructions for Use (IFU) for a complete list of prescribing information. This technique guide was developed in conjunction with health care professionals. Additional information about the medical device is available from Global Biomedica s.r.o.

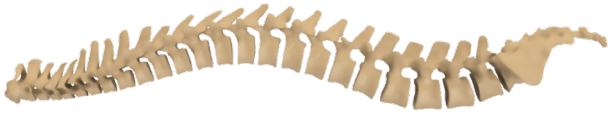


Figure 1
Patient positioning

Preparation and Approach

The patient is placed on the OR table using the standard positioning in cases of Posterior Lumbar Interbody Fusion (Figure 1). Make sure the abdomen is free positioned to avoid pressure on the large vessels and to minimize blood loss. A radiolucent OR table is recommended, as X-ray shall be used to confirm identification of the affected disc and in a later stage the position of the implant. Mark the affected segment after fluoroscopy control. A standard incision is performed over the level(s) to be instrumented. Expose the spinous process and facet joint on the affected side. Use a high-speed drill, or Kerrison rongeur Resect the necessary part of lamina and facet joint to approach the spinal canal, avoid the completely resection of facet joint, if possible.



Figure 2
Endplate preparation

Decompression and Discectomy

To ease the discectomy procedure, insertion of pedicle screws and performing a slight distraction over the pedicle screws prior to the discectomy can be advantageous. The neural foramen and spinal canal are decompressed as necessary. Dural sac is gently retracted medially using a nerve root retractor. The posterolateral portion of the annulus is then exposed and a window is created to gain access to the intervertebral space. The dural sac and neural structures are continually protected by the nerve root retractor. After the disc is cleared, the endplate cartilage should be removed carefully, leaving the upper and lower bony endplate intact (Figure 2). Injury to the bony endplates may lead to implant subsidence.



Figure 3
Intervertebral disc space

Distraction

An adequate distraction of the intervertebral disc space is one of the preconditions for the primary stability required after cage implantation. For this purpose Distractors are available in several heights (Figure 3). Each size of Distractor has grooves, that indicate the length of 24, 28 and 33 mm respectively. It should be considered to start with the smallest size Distractor to avoid over distraction. Apply the Distractor parallel to the intervertebral space and turn clockwise to open up the disc space.



Figure 4
Correct the surface

To obtain parallel distraction, proceed in the counter side with one size bigger until sufficient distraction is achieved. Correct the surface if necessary with the Rasp tool (Figure 4).



Figure 5
Determination the implant size

Determination of Implant Size

Selection of the trial implant depends on the height, width and depth of intervertebral space and the way of patient preparation and anatomy (Figure 5). Choose a test implant that best matches the shape of intervertebral space and insert it into the Trial Holder. Use X-Ray to check the correct position of the test implant, which should fit tightly and accurately into intervertebral space.



Figure 6
Implant mounting

Implant insertion

Open the sterile packaging of the implant size that was determined with the Trial.

Attach the implant to the Inserter:

Place the implant between the tips of the Inserter that fit into the notches on the lateral side of the implant. Screw the implant to the Inserter by final tightening of the screwcap on the back of the Inserter and tighten with hand (Figure 6). Once the implant is blocked on the instrument, it can be implanted into the intervertebral space.



Figure 7
Place the implant

It is recommended to place the implants in pairs (Figure 7). In case of implanting an oblique single implant, it is advisable to use the largest possible footprint available that fits the anatomy.

Gently tap the implant into the intervertebral disc space using the hammer provided in the instrument set. The first implant should not cross the midline in order not to interfere with the second implant.

During implantation it is necessary to retract and protect neural structures by a nerve root retractor. Despite the application of smooth solid titanium surfaces, the rough porous structure potentially increases the risk of soft tissue adherence unless there is sufficient protection. Use the Hexagonal Key to rotate the implant if it needs to be assembled (Figure 8).



Figure 8
Implant rotation

Completion of Surgery

After Implantation of the implant a final check of the position of the implant under fluoroscopy is advised (Figure 9).

Posterior supplemental fixation is strongly recommended. Perform wound closure as usual. Please document which implants were used in the patient files. Patient labels are supplied with each implant for your convenience. The use of the BMD Titanium PLIF Implant[®] does not require any specific postoperative care and the patient should be treated according to hospital and medical standards.

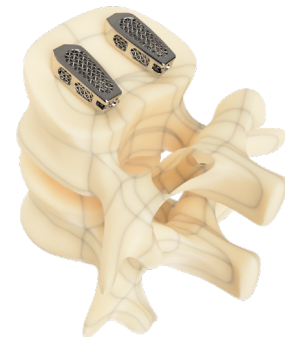


Figure 9
Final position



Figure 10
Implant removal

Implant Removal

Either the Inserter or Universal Removal Instrument may be used for Implant removal by attachment via clockwise rotation to the implant threads (Figure 10). Be careful to avoid pushing the implant posteriorly. Once the implant is firmly attached, remove the implant from the disc space. Vertebral bone overgrowth or osteophytes may be removed to facilitate implant retrieval.

List of implants

DESCRIPTION, D x H x W,	4°	PART NUMBER	DESCRIPTION, D x H x W,	12°	PART NUMBER
PLIF, 24mm x 7mm x 10mm,	4°	BMDP24100704	PLIF, 24mm x 9mm x 10mm,	12°	BMDP24100912
PLIF, 24mm x 8mm x 10mm,	4°	BMDP24100804	PLIF, 24mm x 10mm x 10mm,	12°	BMDP24101012
PLIF, 24mm x 9mm x 10mm,	4°	BMDP24100904	PLIF, 24mm x 11mm x 10mm,	12°	BMDP24101112
PLIF, 24mm x 10mm x 10mm,	4°	BMDP24101004	PLIF, 24mm x 12mm x 10mm,	12°	BMDP24101212
PLIF, 24mm x 11mm x 10mm,	4°	BMDP24101104	PLIF, 24mm x 13mm x 10mm,	12°	BMDP24101312
PLIF, 24mm x 12mm x 10mm,	4°	BMDP24101204	PLIF, 24mm x 14mm x 10mm,	12°	BMDP24101412
PLIF, 24mm x 13mm x 10mm,	4°	BMDP24101304	PLIF, 24mm x 15mm x 10mm,	12°	BMDP24101512
PLIF, 24mm x 14mm x 10mm,	4°	BMDP24101404	PLIF, 24mm x 16mm x 10mm,	12°	BMDP24101612
PLIF, 24mm x 15mm x 10mm,	4°	BMDP24101504	PLIF, 24mm x 17mm x 10mm,	12°	BMDP24101712
PLIF, 28mm x 7mm x 10mm,	4°	BMDP28100704	PLIF, 28mm x 11mm x 10mm,	12°	BMDP28101112
PLIF, 28mm x 8mm x 10mm,	4°	BMDP28100804	PLIF, 28mm x 12mm x 10mm,	12°	BMDP28101212
PLIF, 28mm x 9mm x 10mm,	4°	BMDP28100904	PLIF, 28mm x 13mm x 10mm,	12°	BMDP28101312
PLIF, 28mm x 10mm x 10mm,	4°	BMDP28101004	PLIF, 28mm x 14mm x 10mm,	12°	BMDP28101412
PLIF, 28mm x 11mm x 10mm,	4°	BMDP28101104	PLIF, 28mm x 15mm x 10mm,	12°	BMDP28101512
PLIF, 28mm x 12mm x 10mm,	4°	BMDP28101204	PLIF, 28mm x 16mm x 10mm,	12°	BMDP28101612
PLIF, 28mm x 13mm x 10mm,	4°	BMDP28101304	PLIF, 28mm x 17mm x 10mm,	12°	BMDP28101712
PLIF, 28mm x 14mm x 10mm,	4°	BMDP28101404	PLIF, 33mm x 11mm x 12mm,	12°	BMDP33121112
PLIF, 28mm x 15mm x 10mm,	4°	BMDP28101504	PLIF, 33mm x 12mm x 12mm,	12°	BMDP33121212
PLIF, 33mm x 9mm x 12mm,	4°	BMDP33120904	PLIF, 33mm x 13mm x 12mm,	12°	BMDP33121312
PLIF, 33mm x 11mm x 12mm,	4°	BMDP33121104	PLIF, 33mm x 14mm x 12mm,	12°	BMDP33121412
PLIF, 33mm x 13mm x 12mm,	4°	BMDP33121304	PLIF, 33mm x 15mm x 12mm,	12°	BMDP33121512
PLIF, 33mm x 15mm x 12mm,	4°	BMDP33121504	PLIF, 33mm x 16mm x 12mm,	12°	BMDP33121612
			PLIF, 33mm x 17mm x 12mm,	12°	BMDP33121712
DESCRIPTION, D x H x W,	8°	PART NUMBER	DESCRIPTION, D x H x W,	16°	PART NUMBER
PLIF, 24mm x 7mm x 10mm,	8°	BMDP24100708	PLIF, 24mm x 11mm x 10mm,	16°	BMDP24101116
PLIF, 24mm x 8mm x 10mm,	8°	BMDP24100808	PLIF, 24mm x 12mm x 10mm,	16°	BMDP24101216
PLIF, 24mm x 9mm x 10mm,	8°	BMDP24100908	PLIF, 24mm x 13mm x 10mm,	16°	BMDP24101316
PLIF, 24mm x 10mm x 10mm,	8°	BMDP24101008	PLIF, 24mm x 14mm x 10mm,	16°	BMDP24101416
PLIF, 24mm x 11mm x 10mm,	8°	BMDP24101108	PLIF, 24mm x 15mm x 10mm,	16°	BMDP24101516
PLIF, 24mm x 12mm x 10mm,	8°	BMDP24101208	PLIF, 24mm x 16mm x 10mm,	16°	BMDP24101616
PLIF, 24mm x 13mm x 10mm,	8°	BMDP24101308	PLIF, 24mm x 17mm x 10mm,	16°	BMDP24101716
PLIF, 24mm x 14mm x 10mm,	8°	BMDP24101408	PLIF, 28mm x 13mm x 10mm,	16°	BMDP28101316
PLIF, 24mm x 15mm x 10mm,	8°	BMDP24101508	PLIF, 28mm x 14mm x 10mm,	16°	BMDP28101416
PLIF, 28mm x 7mm x 10mm,	8°	BMDP28100708	PLIF, 28mm x 15mm x 10mm,	16°	BMDP28101516
PLIF, 28mm x 8mm x 10mm,	8°	BMDP28100808	PLIF, 28mm x 16mm x 10mm,	16°	BMDP28101616
PLIF, 28mm x 9mm x 10mm,	8°	BMDP28100908	PLIF, 28mm x 17mm x 10mm,	16°	BMDP28101716
PLIF, 28mm x 10mm x 10mm,	8°	BMDP28101008			
PLIF, 28mm x 11mm x 10mm,	8°	BMDP28101108	DESCRIPTION, D x H x W,	20°	PART NUMBER
PLIF, 28mm x 12mm x 10mm,	8°	BMDP28101208	PLIF, 24mm x 13mm x 10mm,	20°	BMDP24101320
PLIF, 28mm x 13mm x 10mm,	8°	BMDP28101308	PLIF, 24mm x 14mm x 10mm,	20°	BMDP24101420
PLIF, 28mm x 14mm x 10mm,	8°	BMDP28101408	PLIF, 24mm x 15mm x 10mm,	20°	BMDP24101520
PLIF, 28mm x 15mm x 10mm,	8°	BMDP28101508	PLIF, 24mm x 16mm x 10mm,	20°	BMDP24101620
PLIF, 33mm x 9mm x 12mm,	8°	BMDP33120908	PLIF, 24mm x 17mm x 10mm,	20°	BMDP24101720
PLIF, 33mm x 10mm x 12mm,	8°	BMDP33121008	PLIF, 28mm x 15mm x 10mm,	20°	BMDP28101520
PLIF, 33mm x 11mm x 12mm,	8°	BMDP33121108	PLIF, 28mm x 16mm x 10mm,	20°	BMDP28101620
PLIF, 33mm x 12mm x 12mm,	8°	BMDP33121208	PLIF, 28mm x 17mm x 10mm,	20°	BMDP28101720
PLIF, 33mm x 13mm x 12mm,	8°	BMDP33121308			
PLIF, 33mm x 14mm x 12mm,	8°	BMDP33121408			
PLIF, 33mm x 15mm x 12mm,	8°	BMDP33121508			

Tool list

DESCRIPTION D x W x H,	QTY	PART NUMBER	DESCRIPTION D x W x H,	QTY	PART NUMBER
Distractor 7, 1/4	1	35-101	PLIF Trial 8° 1/4, 10 x 7 mm	1	45-689
Distractor 8, 1/4	1	35-102	PLIF Trial 8° 1/4, 10 x 8 mm	1	45-690
Distractor 9, 1/4	1	35-103	PLIF Trial 8° 1/4, 10 x 9 mm	1	45-691
Distractor 10, 1/4	1	35-104	PLIF Trial 8° 1/4, 10 x 10 mm	1	45-692
Distractor 11, 1/4	1	35-105	PLIF Trial 8° 1/4, 10 x 11 mm	1	45-693
Distractor 12, 1/4	1	35-106	PLIF Trial 8° 1/4, 10 x 12 mm	1	45-694
Distractor 13, 1/4	1	35-107	PLIF Trial 8° 1/4, 10 x 13 mm	1	45-695
Distractor 14, 1/4	1	35-108	PLIF Trial 8° 1/4, 10 x 14 mm	1	45-696
Distractor 15, 1/4	1	35-109	PLIF Trial 8° 1/4, 10 x 15 mm	1	45-697
Curette D9L5	1	35-110	Instrument Basket	1	45-400
Curette 45° D9L5	1	35-111	Trial Basket PLIF	1	45-401
Curette 15° D5L3	1	35-112	PLIF Trial 12° 1/4, 10 x 9 mm	1	45-698
Curette 15° D9L5	1	35-113	PLIF Trial 12° 1/4, 10 x 10 mm	1	45-699
T-Handle	2	35-114	PLIF Trial 12° 1/4, 10 x 11 mm	1	45-700
Mallet	1	35-115	PLIF Trial 12° 1/4, 10 x 12 mm	1	45-701
Rasp	1	35-116	PLIF Trial 12° 1/4, 10 x 13 mm	1	45-702
Distractor 16, 1/4	1	35-117	PLIF Trial 12° 1/4, 10 x 14 mm	1	45-703
Distractor 17, 1/4	1	35-118	PLIF Trial 12° 1/4, 10 x 15 mm	1	45-704
Trial Basket	1	35-120	PLIF Trial 12° 1/4, 10 x 16 mm	1	45-705
Final Impactor	1	45-101	PLIF Trial 12° 1/4, 10 x 17 mm	1	45-706
Hexagonal Key	1	45-102	PLIF Trial 16° 1/4, 10 x 11 mm	1	45-707
Cage Holder	2	45-103	PLIF Trial 16° 1/4, 10 x 12 mm	1	45-708
Cage Slider 1/4	1	45-104	PLIF Trial 16° 1/4, 10 x 13 mm	1	45-709
PLIF Trial 4° 1/4, 10 x 7 mm	1	45-680	PLIF Trial 16° 1/4, 10 x 14 mm	1	45-710
PLIF Trial 4° 1/4, 10 x 8 mm	1	45-681	PLIF Trial 16° 1/4, 10 x 15 mm	1	45-711
PLIF Trial 4° 1/4, 10 x 9 mm	1	45-682	PLIF Trial 16° 1/4, 10 x 16 mm	1	45-712
PLIF Trial 4° 1/4, 10 x 10 mm	1	45-683	PLIF Trial 16° 1/4, 10 x 17 mm	1	45-713
PLIF Trial 4° 1/4, 10 x 11 mm	1	45-684	PLIF Trial 20° 1/4, 10 x 13 mm	1	45-714
PLIF Trial 4° 1/4, 10 x 12 mm	1	45-685	PLIF Trial 20° 1/4, 10 x 14 mm	1	45-715
PLIF Trial 4° 1/4, 10 x 13 mm	1	45-686	PLIF Trial 20° 1/4, 10 x 15 mm	1	45-716
PLIF Trial 4° 1/4, 10 x 14 mm	1	45-687	PLIF Trial 20° 1/4, 10 x 16 mm	1	45-717
PLIF Trial 4° 1/4, 10 x 15 mm	1	45-688	PLIF Trial 20° 1/4, 10 x 17 mm	1	45-718

Important information on the Global BMD Titanium Implant[®]

Device Description and Materials

Global Biomedica offers spinal surgery implants with excellent biocompatibility and bioactivity. We use the latest innovative technologies to create a line of spinal BMD Titanium Implant[®]. These are implant for interbody fusion of biocompatible titanium (Ti64ELI). Internal and surface grid structure with optimum pore size of 700µm (Cube vertex centroid - lattice) with reinforced edges ensures not only high stability and resistance to deformation of the implant, or immersion in the vertebral body, but also bioactivity - potentiates the formation of bone in the area of contact surfaces and thus the formation of a strong connection between the implant and bone, the risk of developing non union (pseudoarthrosis) is thus minimized.

Indication for Use

The lumbar BMD Titanium Implant[®] is indicated for lumbar interbody fusion for the following indications:

- Degenerative and postoperative spinal involvement in term of rupture, osteochondrosis, degenerative stenosis, pseudarthrosis
- Traumatic disc involvement – only in the absence of traumatic vertebrae involvement and significant ligament instability of posterior column.

Contraindications

The lumbar BMD Titanium Implant[®] should not be used in patients with any of the following contraindications (Contraindications include, but are not limited). Infection or progressive infection, fever or inflammation.

- Obesity
- Insanity
- Allergy for any of system components
- Any anatomical, medical or surgical conditions that may prevent the potential or intentional benefits of using spinal implants
- Bone, joint or ligament conditions such as: Osteolytic involvement, bone absorption, osteomalacia. Osteopenia and osteoporosis is a relative contraindication and a thorough assessment of the situation is required before performing surgery
- Implant size, shape or functionality of the anchor may not be sufficient to achieve the expected clinical results
- Any risk of patient unwillingness to follow postoperative instructions
- Any other than described indications

Warnings And Precautions

- The effectiveness and safety of interbody fusion is only applicable for certain conditions with significant instability which require the fusion supported by medical device.
- Correct placement and appropriate size selection are crucial to achieve optimal results.
- The device might be supportive for such mechanical instability like deformity, fracture, listhesis, dislocation, tumor, pseudoarthrosis. The effectiveness and safety for any other conditions are unknown.
- BMD Titanium Implant[®] may be supported by additional fixation device. In some cases additional fixation device is highly recommended.
- The contemporary applications of pedicular fixation must be performed by experienced surgeons with specific training in usage BMD Titanium Implant[®].
- The spinal screw fixation system and/or interbody cage system should not be considered as sole spinal support. No implants can withstand body loads without bone support.
- Over the time bends, breakages, loosening, migration may occur. Successful results are not always achievable. The factors as proper pre-operative and operative procedure, comprehensive knowledge or surgical techniques, proper selection of implant's size and type are considerably important in treatment process.
- Patients with obesity, smokers, alcohol abused are enhanced risk of non-fusion. Also patients in weak muscle or bone conditions, nervous system dysfunctions are poor candidates for spinal fusion.
- Prior or during or after the surgery in order to evaluate or check positioning of the implants or patients anatomy or any other patients or implants X-ray or CT or any other invasive diagnostic examinations may be necessary to be performed.
- The proper, patient's individual implants selection in terms of type, size, shape or instruments handling is crucial.
- Extensive bending or contouring should be avoided.
- Sharp edges cutting, reversed bending, scratching or notching may generate internal stressing which may weak the implants or construct.

Potential Adverse Effects

Potential adverse events which may occur after the spinal surgery with or without instrumentation include, but are not limited:

- Breaking, bending, and/or breakage of any or all of the system components.
- Migrations of any system components.
- Pressure on the skin from component parts in patients with inadequate tissue coverage.
- Tissue or nerve damage caused by improper positioning and placement of implants or instruments.
- Damage and leakage of the hard arachnoid, leakage of coeliolymph.
- Neurological dysfunctions such as paresthesia, radiculopathy, paralysis, hyperesthesia or any others related to general surgery associated to anesthesia.
- Infections.
- Loss of urinary and defaecate functions.
- Permanent or temporary or developing sexual dysfunctions.
- Postoperative change in body curvature, change of physiological range of movement.
- Pseudarthrosis or non-fusion or delayed fusion.
- Loss of bone or overgrowth.
- Permanent or temporary limitation or inability to perform daily activities.
- Changing in mental behavior.
- Permanent or temporary or developing respiratory problems.
- Permanent or temporary or developing cardiovascular deteriorations or dysfunctions.
- Death.


In some cases additional surgery or surgeries might be necessary to correct or change potential adverse events.


IMPORTANT NOTICE: All necessary information on surgery, potential risks, benefits and adverse effects must be reported to the patient prior to surgery.



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Disclaimer: This document is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is recommendations. Because this information does not purport to constitute any diagnostics or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part.

 Caution: Please see the product Instructions for Use for a complete listing of the indications, contraindications, precautions, warnings and adverse effects.

 **MANUFACTURER**
GLOBAL BIOMEDICA s.r.o., Ostravská 555/24,
737 01 Český Těšín, Czech Republic, info@globalbmd.com

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